REMARKS

Claims 1-20 are now pending in the application. The Examiner is respectfully requested to reconsider and withdraw the rejection in view of the amendments and remarks contained herein.

REJECTION UNDER 35 U.S.C. § 102

Claims 1-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hollister et al. ("*A Homogenization Sampling Procedure For Calculating Trabecular Bone Effective Stiffness And Tissue Level Stress*"). This rejection is respectfully traversed.

In the most recent Office Action, the Examiner has generally referenced portions of Hollister et al. (1994) as teaching elements of the currently pending claims. However, in most cases, Applicant is unable to ascertain any such teaching in the cited reference. Specifically, claims of the present application include elements directed to "weighting factors", "ratios", "thermal conductivity", "electrical conductivity", etc. However, Applicant submits that none of these elements are taught or suggested in Hollister et al. (1994). Therefore, Applicant requests the Examiner specifically cite with particularly the teachings within Hollister et al. (1994) that substantiate the present rejection so that Applicant will have an opportunity to refute such assertions. Applicant submits that the Examiner has failed to meet the burden of proof necessary to reject each of the pending claims and believes that should the Examiner maintain rejection of the present application that any subsequent Office Action should not be made Final.

Claim 1:

At the outset, Applicant wishes to note that independent Claim 1 claims "creating a material density distribution map based on an initial device design shape, said material density distribution map having discrete points; determining a numerical weighting factor based on a predicted time-based elastic or molecular weight degradation pattern; weighting said material density distribution map using said numerical weighting factor to determine a weighted density distribution map; and using said weight density distribution map to determine a material reinforcement of said device to create a final device design shape such that said device will retain predetermined structural properties during a material degradation lifecycle."

As discussed in the originally filed application, the use of biodegradable material for tissue augmentation/reconstruction devices has become increasing prevalent to facilitate tissue regeneration and improve integration with host tissues. Compared to metallic devices, the current trend in using synthetic materials for biodegradable and/or bioresorbable tissue augmentation and/or reconstruction devices has substantially improved the art. These synthetic materials significantly improved fusion compared to conventional titanium cages. However, there was a concern that degradable spine cages lack sufficient load bearing capability compared to titanium cages, especially given the fact that biodegradable and/or bioresorbable cages will lose stiffness and strength over time. Because the base material stiffness will undergo persistent reduction through the degradation lifecycle, merely replacing a non-degradable material with a degradable material in the same design may not produce a device that retains sufficient load bearing capability over a predetermined duration.

In the present invention, the method of integrated topology optimization incorporated with weighing factor design is used to ensure that biodegradable devices have sufficient mechanical properties initially and during degradation. Prolonging stiffness through the degradation was achieved by weighting material density at discrete points to compensate for reduced base material stiffness and lost structural features caused by the bulk erosion (i.e. biodegradation and/or bioresorbtion) . The method of the present application can be applied to any degradable medical device, including but not limited to spine fusion, spine disc devices, hip and knee reconstruction devices, vascular stents, cardiac assist devices, and nerve guidance channels.

As the Examiner is aware, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicant submits that Hollister et al. (1994) fails to teach or suggest each and every element set forth in independent Claim 1. Specifically, Applicant submits that Hollister et al. (1994) merely teaches an analysis method (i.e. image-based homogenization theory) for the estimate of effective macroscopic elastic properties of trabecular bone alone. As the Examiner will appreciate, trabecular bone is a naturally occurring bone tissue. Moreover, it should be appreciated that the microstructure of the trabecular bone of Hollister et al. (1994) is defined *a priori*. It should also be understood that Hollister et al. (1994) is limited to merely an analysis method of bone growth. However, Hollister et al. (1994) is silent with regard to the design and/or manufacture (independent Claim 16) of a biodegrading and/or bioresorbing device.

More particularly, Hollister et al. (1994) is silent with regard to "determining a numerical weighting factor based on a predicted time-based elastic or molecular weight degradation pattern; weighting said material density distribution map using said numerical weighting factor to determine a weighted density distribution map; and using said weight density distribution map to determine a material reinforcement of said device to create a final device design shape such that said device will retain predetermined structural properties during a material degradation lifecycle" as claimed in independent Claim 1.

Claim 2:

Briefly, Applicant wishes to note that dependent Claim 2 claims "said material density distribution map is created using a technique chosen from the group consisting essentially of topology optimization, microstructure topology optimization, restricted topology optimization, image-based design, and computer-aided design techniques." Each of the aforementioned techniques is a design technique. In contrast, the homogenization method described in Hollister et al. (1994) is an analysis method and does not result in a material density distribution map.

Claim 3:

Applicant submits that Hollister et al. (1994) is silent with regard to "topology optimization having an algorithm employed to define said material density distribution map at predetermined time points during said material degradation lifecycle." In contrast, the homogenization method described in Hollister et al. (1994) is an analysis

method and does not result in a material density distribution map. Moreover, Hollister et al (1994) is silent with regard to any degradation cycle, let along a "material degradation lifecycle."

Claim 4:

Applicant submits that Hollister et al. (1994) is silent with regard to "image-based design ~~includes~~ defining said material density distribution map at predetermined time points during said material degradation lifecycle." In contrast, the homogenization method described in Hollister et al. (1994) is an analysis method and does not result in a material density distribution map. Moreover, Hollister et al. (1994) is silent with regard to any degradation cycle, let alone a "material degradation lifecycle."

Claim 5:

Applicant submits that Hollister et al. (1994) is silent with regard to "general computer aided design techniques include defining said material density distribution map at predetermined time points during said material degradation lifecycle." In contrast, the homogenization method described in Hollister et al. (1994) is an analysis method and does not result in a material density distribution map. Moreover, Hollister et al. (1994) is silent with regard to any degradation cycle, let alone a "material degradation lifecycle."

Claim 6:

Applicant submits that Hollister et al. (1994) is silent with regard to "a linear weighting factor, a nonlinear weighting factor, a time past degradation factor, and a ratio of a degraded material property to initial material property." Hollister et al. (1994) is not concerned with any "degradation", let alone that specifically claimed herein.

Claim 7:

Applicant submits that Hollister et al. (1994) is silent with regard to "a ratio of a degraded modulus to an initial modulus." Applicant requests additional specificity as to where such ratio is found in Hollister et al. (1994).

Claim 8:

Applicant submits that Hollister et al. (1994) is silent with regard to "a ratio of a degraded strength to an initial strength." Applicant requests additional specificity as to where such ratio is found in Hollister et al. (1994).

Claim 9:

Applicant submits that Hollister et al. (1994) is silent with regard to "a ratio of a degraded thermal conductivity to an initial thermal conductivity." Applicant requests additional specificity as to where such ratio is found in Hollister et al. (1994).

Claim 10:

Applicant submits that Hollister et al. (1994) is silent with regard to "a ratio of a degraded electrical conductivity to an initial electrical conductivity." Applicant requests additional specificity as to where such ratio is found in Hollister et al. (1994).

Claim 11:

Applicant submits that Hollister et al. (1994) is silent with regard to "superposing said material density distribution map at predetermined time points using both time, degraded base stiffness, and said weighting factor." Applicant requests additional specificity as to where such method step is found in Hollister et al. (1994).

Claim 12:

Applicant submits that Hollister et al. (1994) is silent with regard to "superposing said material density distribution map at predetermined time points using density at a global anatomic level. " Applicant requests additional specificity as to where such method step is found in Hollister et al. (1994).

Claim 13:

Applicant submits that Hollister et al. (1994) is silent with regard to "superposing said material density distribution map at predetermined time points using density at a physical size smaller than said global anatomic level." Applicant requests additional specificity as to where such method step is found in Hollister et al. (1994).

Claim 14:

Applicant submits that Hollister et al. (1994) is silent with regard to "employing material degradation kinetics to enhance said material density distribution map." Applicant requests additional specificity as to where such method step is found in Hollister et al. (1994).

Claim 15:

Applicant submits that Hollister et al. (1994) is silent with regard to "employing material degradation kinetics further comprises employing one chosen from the group consisting essentially of polylactic acid, polyglycolic acid, polyanhdyride, polycaprolactone, tri-calcium phosphate, and hydrogels." Hollister et al. (1994) relates to analysis of naturally occurring bone tissue. Therefore, Applicant requests additional specificity as to where such information regarding synthetic, engineering materials can be found in Hollister et al. (1994).

Claims 16:

At the outset, Applicant wishes to note that independent Claim 16 relates to a method of manufacturing a biodegradable material for tissue augmentation/reconstruction device. The claim specifically claims "dividing the device into elements having a predicted material density between 0 and 1; weighting each predicted material density by a predetermined degradation profile to define a weighted material density, said degradation profile being unique to a material used; and calculating a material weight in each of said element by applying a time lasting factor

and a degrading modulus factor such that high load bearing regions within said device are reinforced to compensate for subsequent stiffness degradation due to bulk erosion of said device."

Applicant respectfully directs the Examiner's attention to the arguments set forth above. Moreover, Applicant submits that Hollister et al. (1994) is silent with regarding to manufacturing of any device whatsoever. Therefore, it is unclear to Applicant wherein Hollister et al. (1994) the Examiner allegedly finds teaching related to "*weighting each predicted material density by a predetermined degradation profile to define a weighted material density, said degradation profile being unique to a material used; and calculating a material weight in each of said element by applying a time lasting factor and a degrading modulus factor such that high load bearing regions within said device are reinforced to compensate for subsequent stiffness degradation due to bulk erosion of said device.*" These method steps uniquely provide enhancements to a manufactured good and do not relate to analyzing existing bone tissue. The Examiner globally references Equations 1 and 2 of Hollister et al. (1994). However, these equations are silent with regard to the claimed manufacturing steps. Therefore, Applicant requests additional specificity as to where such method steps are found in Hollister et al. (1994).

For at least these reasons, Applicant submits that the claims of the present application are in condition for allowance. Reconsideration and withdrawal of the present rejection are respectfully requested. In the event that the Examiner elects to maintain the present rejection, Applicant requests the Examiner state with particularity

the teachings of Hollister et al. (1994) that allegedly anticipate each and every element of the pending claims for purposes of appeal.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: December 21, 2010

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